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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,647	07/30/2001	Kenichi Arai	2001-0531A	1900

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/830,647

Applicant(s)

ARAI ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Priority*

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09830647, filed on 7/30/2001.

3. The disclosure is objected to because of the following informalities: The claims define the scope of an invention and must particularly point out and distinctly claim the invention, and must contain a single sentence starting "I (We) claim:" or "What is claimed is:" Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

OK Claims 1-5 are rejected under 35 U.S.C. 101 because the claims read on the protein and the gene *per se* which is found in nature and thus, is unpatentable to applicant. It is suggested that the applicant use the language –isolated—or –purified—in connection with the proteins of claims 1-4 and the human gene of claim 5. Consequently, the claims do not embody patentable subject matter as defined in 35 USC 101. See MPEP 2105.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8-9, 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to the recitation of the term "partial sequence," it is unclear as to the metes and bounds of the sequence. Currently, the claims reads as any DNA sequence having similarity to Seq ID No. 3 or 4 without any limitations to homology. In other words, a match of 10 nucleic acids is enough to encompass sequence similarity.

7. Claims 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16-17 are directed at methods for suppressing the proliferation of cells using an antibody of claims 10-11. Claims 10-11 refer to recombinant vectors. Claims 16-17 are unclear, and clarification is required.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims ~~2,4,6,7-9~~, 12-15, are rejected under 35 U.S.C 112, first paragraph, because the specification does not provide enablement for the deletion or substitution of 1 or more amino acids. The specification only mentions polymorphisms and variations associated with human allelic differences. The specification does not disclose the making or use of these additions, deletions or substitutions. This would lead one of skill in the art into undue experimentation to ascertain how many modifications either in

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additions, deletions, or substitutions of amino acids needed to maintain the functional activity of an H37 protein.

In addition, one of skill in the art would find it difficult to know where the additions, deletions or substitutions would be placed to retain the functional activity of the H37 protein. Furthermore, once the modifications of either addition, deletion, or substitutions are accomplished, one of skill in the art would be forced into undue experimentation to screen for H37 proteins with additions, deletions, or substitutions. One would also find it difficult to know what type of screening criteria is to be used to signify to one skilled in the art that the modified protein has the same functional activity as H37 protein. The specification does not disclose this feature to enable the modifications as claimed in this invention.

10. Claims 8-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the full length nucleic acid sequence disclosed in Seq ID No. 3 and 4, does not reasonably provide enablement for partial sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification does not allow one of skill in the art to know the exact limitations of the sequence (i.e. homology overlap), whether 10% homology with the sequence as disclosed in SEQ ID No. 3 or 4 is enough to constitute a partial sequence.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 1-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Kumagai H. *et al.* (Mol Cell Biol. 1999 Jul;19(7):5083-95.).

ND Kumagai H *et al.* teach the identification of a novel growth and cell cycle regulated protein, termed ASK or activator of S phase kinase. The protein, ASK, is the same protein disclosed in the current application, H37.

13. Claims 5-7 are rejected under 35 U.S.C 102(e) as being anticipated by Shimkets RA *et al.* (WO200058473-A2). Shimkets RA *et al.* teaches a nucleic acid sequence which is identical to that disclosed in the current application. Shimkets RA *et al.* further teaches the use of this nucleic acid sequence in the treatment of proliferative disorders. OK It would be expected and anticipated that a gene encoding human H37 protein and a cDNA sequence as claimed in claims 5-7 would have the same or similar features as that taught by Shimkets *et al.*

14. Claims 8-9 are rejected under 35 U.S.C 102(e) as being anticipated by Penn SG *et al.* (WO200157278-A2). Penn SG *et al.* teaches a single exon nucleic acid probe OK which is mostly identical with the sequences disclosed in claims 8-9, which is directed at a partial nucleic acid sequence of cDNA. It is anticipated that this partial sequence of claims 8 and 9, is identical to that disclosed in Penn SG *et al.* because there is greater

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than 99% sequence homology match. Any sequence chosen within this matching region of Penn SG *et al.* is considered a partial sequence that is identical to the sequence of claims 8 and 9. It is further anticipated that the partial sequence of claims 8 and 9 would have the same or similar features as taught by Penn SG *et al.*

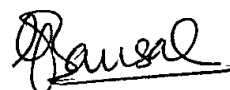
**Conclusion**

15. No Claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
GEETHA P. BANSAL  
PRIMARY EXAMINER

Christopher Yaen  
Art Unit 1642  
January 14, 2002